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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,694	05/22/2000	Anne Sorensen	Novo-029	3706

23650 7590 05/08/2007

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PATENT DEPARTMENT
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EXAMINER	
HON, SOW FUN	
ART UNIT	**PAPER NUMBER**
1772	

NOTIFICATION DATE	DELIVERY MODE
05/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/577,694	SORENSEN ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-74 and 77-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-74 and 77-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Withdrawn Rejections

1. The objection and rejections under 35 U.S.C. 112, 2nd paragraph and 103(a) of claim 75, are withdrawn due to Applicant's cancellation of said claim.

2. The 35 U.S.C 103(a) rejection of claim 76 is withdrawn due to Applicant's cancellation of said claim.

3. The 35 U.S.C. 103(a) rejections of claims 63-74, 77-85 over Kasai275 (US 4,664,275) as the primary reference, are withdrawn in light of Applicant's arguments which are deemed persuasive. However, further consideration of Kasai275 resulted in the new grounds of rejection presented below.

New Rejections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 63-68, 71-74, 77-81, 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai (US 4,664,275).

Regarding claims 63, 67, Kasai teaches a stopper (column 4, lines 33-35) comprising an injection-mouldable material (can be injection-molded, column 5, lines 47-48), comprising: a blend (mixed by a mixer, column 4, lines 38-40) of a butyl based rubber and a polyolefin (polyethylene, Examples 1-5, column 4, lines 50-70), wherein

the butyl based rubber is present in an amount of 30 to 80% by weight (column 1, lines 64-66), which overlaps the claimed range of 70-90%, or 75-87%, by weight; and the polyolefin is present in an amount of 10 to 40% by weight (thermoplastic resin, column 2, lines 26-29, examples of such thermoplastic resins may include polyethylene, column 2, lines 43-45), which encompasses the claimed range of 30-10%, or 13-25%, by weight; wherein the combination of the butyl based rubber and the polyolefin results in a reduced leakage of substances compared to the leakage of substances from a stopper made from butyl based rubber alone (can maintain a reduced internal pressure for a longer period of time than can a conventional stopper, column 5, lines 39-46, a butyl stopper is conventionally used, column 1, lines 15-18). Kasai teaches that the injection-mouldable material further comprises a lower amount of 5% by weight of inorganic powder, wherein the powder inherently functions as a filler (column 2, lines 54-61), which is within the claimed range of 10% by weight or less of fillers. By teaching that the stopper material has the composition described above, and that "however, the composition can further contain additives" (column 3, lines 8-10), Kasai teaches that the additives are optional, which means that the amount of additives can then be zero, which is within the range of 1% or less. Kasai teaches that the prior art stopper comprising butyl based rubber and thermoplastic elastomer is free from the problem encountered with butyl based rubber alone, but still has problems with compression set (column 1, lines 25-35), meeting the claimed proviso that the injection-mouldable material comprises other than a thermoplastic elastomer. Kasai fails to provide any

examples of the injection-mouldable material with the claimed combination of weight% ranges of the fillers and additives.

However, Kasai teaches that the injection-mouldable material components with the combination of weight% ranges overlapping the claimed weight% ranges, in the detailed description of preferred embodiments, as described above, are used to reduce compression set, provide good gas (column 1, lines 65-68) barrier performance, decrease hardness (column 2, lines 1-2), good moldability (column 2, lines 26-31), and other physical properties, for the purpose of providing a stopper with the desired combination of longer internal pressure hold, reduced compression set, good fit and temperature resistance (column 5, lines 40-46). Thus Kasai establishes that the combination of weight% ranges of the injection-mouldable material components, is a variable that can be varied to achieve the desired combination of longer internal pressure hold, reduced compression set, good fit and temperature resistance.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have modified the combined weight % ranges of the injection-mouldable material components of the stopper composition of Kasai, to obtain the claimed combination, in order to provide the desired combination of longer pressure hold, reduced compression set, good fit and temperature resistance, as taught by Kasai.

Regarding claims 64-66, Kasai fails to teach the Shore A hardness of the stopper.

However, Kasai teaches that the stopper composition is homogenized with heating (mixed at 130°C to 180°C, column 3, lines 20-24), and the stopper is then

injection moulded (at 180°C to 220°C, column 3, lines 24-25), wherein since injection moulding requires the blend to be fluid, injection moulding at 220 °C means that the thermoplastic polypropylene or polyethylene is in the melt. Hence the process steps of stopper manufacture, and not just the stopper composition, are similar to those described in Applicant's specification (page 2, lines 25-30). Kasai teaches that the butyl rubber is blended with at least 10% by weight of polypropylene or polyethylene (column 2, lines 26-31, 40-46), which is varied to provide the stopper with the desired mouldability (column 2, lines 26-31) balanced with the desired hardness (column 2, line 33). Thus Kasai establishes that the stopper hardness is a cause-effective variable.

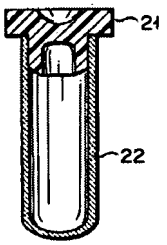
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have optimized the process of manufacturing the stopper of Kasai, to obtain a hardness of 40-80 Shore A, 45-75 Shore A, or 65-75 Shore A, in order to provide the desired stopper performance, as taught by Kasai.

Regarding claim 68, Kasai teaches that the polyolefin is selected from the group of polyolefins consisting of polypropylene and polyethylene (column 2, lines 40-47).

Regarding claim 71, Kasai teaches that the butyl based rubber is at least partially crosslinked (column 1, lines 65-66).

Regarding claim 72, in Fig. 5 of Kasai, shown on the next page, the stopper (21, column 4, lines 26-31) has a substantially circular cross-section.

F I G. 5



Regarding claims 73-74, Kasai teaches a medical container with non-flexible walls (hard, column 5, lines 42-45). In Fig. 5 of Kasai, shown above, the container 22 comprises a distal and a proximal end, and at least one wall defining an interior space for storing liquid blood (column 5, lines 39-40), and hence alternately liquid medicament since the medical container can also store medicament (drug, column 1, lines 12-13), wherein one of the end portions of the medical container comprises a stopper (21, column 4, lines 26-31). Kasai teaches a stopper (column 4, lines 33-35) comprising an injection-mouldable material (can be injection-molded, column 5, lines 47-48), comprising: a blend (mixed by a mixer, column 4, lines 38-40) of a butyl based rubber and a polyolefin (polyethylene, Examples 1-5, column 4, lines 50-70), wherein the butyl based rubber is present in an amount of 30 to 80% by weight (column 1, lines 64-66), which overlaps the claimed range of 70-90%, or 75-87%, by weight; and the polyolefin is present in an amount of 10 to 40% by weight (thermoplastic resin, column 2, lines 26-29, examples of such thermoplastic resins may include polyethylene, column 2, lines 43-45), which encompasses the claimed range of 30-10%, or 13-25%, by weight; wherein the combination of the butyl based rubber and the polyolefin results in a reduced leakage of substances compared to the leakage of substances from a stopper

made from butyl based rubber alone (can maintain a reduced internal pressure for a longer period of time than can a conventional stopper, column 5, lines 39-46, a butyl stopper is conventionally used, column 1, lines 15-18). Kasai teaches that the injection-mouldable material further comprises a lower amount of 5% by weight of inorganic powder, wherein the powder inherently functions as a filler (column 2, lines 54-61), which is within the claimed range of 10% by weight or less of fillers. By teaching that the stopper material has the composition described above, and that "however, the composition can further contain additives" (column 3, lines 8-10), Kasai teaches that the additives are optional, which means that the amount of additives can then be zero, which is within the range of 1% or less. Kasai teaches that the prior art stopper comprising butyl based rubber and thermoplastic elastomer is free from the problem encountered with butyl based rubber alone, but still has problems with compression set (column 1, lines 25-35), meeting the claimed proviso that the injection-mouldable material comprises other than a thermoplastic elastomer.

It is noted that the recitation of "for storing a liquid medicament" is an intended use one, and is not a positive recitation since a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Kasai fails to provide any examples of the injection-mouldable material with the claimed combination of weight% ranges of the fillers and additives.

However, Kasai teaches that the injection-mouldable material components with the combination of weight% ranges overlapping the claimed weight% ranges, in the detailed description of preferred embodiments, as described above, are used to reduce compression set, provide good gas (column 1, lines 65-68) barrier performance, decrease hardness (column 2, lines 1-2), good moldability (column 2, lines 26-31), and other physical properties, for the purpose of providing a stopper with the desired combination of longer internal pressure hold, reduced compression set, good fit and temperature resistance (column 5, lines 40-46). Thus Kasai establishes that the combination of weight% ranges of the injection-mouldable material components, is a variable that can be varied to achieve the desired combination of longer internal pressure hold, reduced compression set, good fit and temperature resistance.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have modified the combined weight % ranges of the injection-mouldable material components of the stopper composition of Kasai, to obtain the claimed combination, in order to provide the desired combination of longer pressure hold, reduced compression set, good fit and temperature resistance, as taught by Kasai.

Regarding claims 77, 80, Kasai teaches a stopper (column 4, lines 33-35) comprising an injection-mouldable material (can be injection-molded, column 5, lines 47-48), consisting essentially of: a blend (mixed by a mixer, column 4, lines 38-40) of a butyl based rubber and a polyolefin (polyethylene, Examples 1-5, column 4, lines 50-70), wherein the butyl based rubber is present in an amount of 30 to 80% by weight (column 1, lines 64-66), which overlaps the claimed range of 70-90%, or 75-87%, by

weight; wherein additives are optionally present (however, the composition can further contain additives, column 3, lines 8-10) in an amount from 20 phr or less to 5 phr or less (column 3, lines 15-18), and hence have an amount of zero, which is within the claimed range of not exceeding 1% by weight, and an inorganic powder which functions as a filler, in an amount at the low end of 5% by weight (column 1, lines 49-51) which is within the claimed range of less than 10% by weight. Kasai teaches that the polyolefin is present in an amount of 10 to 40% by weight (thermoplastic resin, column 2, lines 26-29, examples of such thermoplastic resins may include polyethylene, column 2, lines 43-45), which encompasses the claimed range of 13-25%, by weight, and which is the balance of the injection-mouldable material (additives added based on the total weight of the butyl rubber and the thermoplastic resin, column 3, lines 15-16); wherein the combination of the butyl based rubber and the polyolefin results in a reduced leakage of substances compared to the leakage of substances from a stopper made from butyl based rubber alone (can maintain a reduced internal pressure for a longer period of time than can a conventional stopper, column 5, lines 39-46, a butyl stopper is conventionally used, column 1, lines 15-18).

Regarding claims 78-79, Kasai fails to teach the Shore A hardness of the stopper.

However, Kasai teaches that the stopper composition is homogenized with heating (mixed at 130°C to 180°C, column 3, lines 20-24), and the stopper is then injection moulded (at 180°C to 220°C, column 3, lines 24-25), wherein since injection moulding requires the blend to be fluid, injection moulding at 220 °C means that the

thermoplastic polypropylene or polyethylene is in the melt. Hence the process steps of stopper manufacture, and not just the stopper composition, are similar to those described in Applicant's specification (page 2, lines 25-30). Kasai teaches that the butyl rubber is blended with at least 10% by weight of polypropylene or polyethylene (column 2, lines 26-31, 40-46), which is varied to provide the stopper with the desired mouldability (column 2, lines 26-31) balanced with the desired hardness (column 2, line 33). Thus Kasai establishes that the stopper hardness is a cause-effective variable.

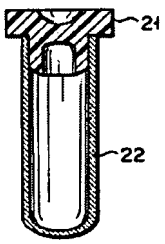
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have optimized the process of manufacturing the stopper of Kasai, to obtain a hardness of 40-80 Shore A, 45-75 Shore A, or 65-75 Shore A, in order to provide the desired stopper performance, as taught by Kasai.

Regarding claim 81, Kasai teaches that the polyolefin is selected from the group of polyolefins consisting of polypropylene and polyethylene (column 2, lines 40-47).

Regarding claim 84, Kasai teaches that the butyl based rubber is at least partially crosslinked (column 1, lines 65-66).

Regarding claim 85, in Fig. 5 of Kasai, shown below, the stopper (21, column 4, lines 26-31) has a substantially circular cross-section.

F I G. 5



5. Claims 69-70, 82-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai (US 4,664,275) as applied to claims 63-68, 71-74, 77-81, 84-85 above, and further in view of Kasai (US 4,444,330).

K275 (Kasai, US 4,664,275) teaches the stopper comprising the injection-mouldable material comprising butyl based rubber, as discussed above. K275 fails to teach that the butyl based rubber is bromobutyl, which is a halogenated butyl.

However, K330 (Kasai, US 4,444,330) teaches a stopper comprising injection-mouldable material (abstract) comprising butyl based rubber which is a halogenated one (column 1, lines 50-55) such as a bromobutyl rubber (column 2, line 65), for the purpose of utilizing the physical properties provided by the halogenation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used a halogenated butyl based rubber, such as a bromobutyl rubber, as the butyl based rubber in the stopper of K275, in order to provide the stopper with the physical properties given to the butyl rubber by the bromination, as taught by K330.

Response to Arguments

6. Applicant's arguments regarding Kasai275 and Kasai330 are addressed in light of the new rejections, in order to further advance prosecution.

7. Applicant argues that Kasai275 states clearly that in order to impart a still improved gas barrier performance to the stopper of the present invention, the stopper

material further contains 5 to 50% by weight of an inorganic [powder], wherein the powder is a necessary additive in order to make the stopper function correctly, while Applicant's own specification teaches that the stopper can have no more than 1% additives while Kasai275 requires at least 5% additives, and thus teaches away from Applicant's invention.

Applicant is respectfully apprised that the inorganic powder of Kasai275 can function as a filler for the stopper, so that the lower amount of 5% by weight of inorganic powder (column 2, lines 54-61) is within the range of 10% by weight or less of filler. By teaching that the stopper material has the composition described above, and that "however, the composition can further contain additives" (column 3, lines 8-10), Kasai teaches that the additives are optional, which means that the amount of additives can then be zero, which is within the range of 1% or less.

8. Applicant argues that Kasai330 teaches that the thermoplastic is an elastomer and that at least 10% elastomer is needed and that the elastomer cannot exceed 70%, and thus the two Kasai references teach away from the claimed invention.

Applicant is respectfully apprised that Kasai275 is the primary reference that teaches the thermoplastic that is not an elastomer (polyethylene, column 2, lines 43-45). Kasai330 is the secondary reference that teaches that the butyl rubber of Kasai275 can be specifically a bromobutyl rubber for the purpose of utilizing the physical properties given to the butyl rubber by the bromination.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon

Sow-Fun Hon

04/18/07

RENA DYE
SUPERVISORY PATENT EXAMINER
Technology Center
1733